Application No. 10/537,118

Amendment dated June 9, 2011

Reply to the Office Action dated December 9, 2010

#### REMARKS

The Office Action of December 9, 2010, presents the examination of claims 1, 4-6, 19, 29, 30 and 40, claims 7-18, 20-28, 31-34 and 39 being withdrawn from consideration following restriction and/or election of species.

The claims are amended solely to add their IDAC accession numbers. Therefore, no new matter has been added.

# Request by the Examiner

On page 3 of the Office Action, the Examiner asks Applicants to provide "a list of keywords, ATCC accession numbers, other names by which the bacterial strains are known in the art or any other identifying information by which one skilled in the art would be able to distinguish the claimed strains." The Examiner has formally made this request pursuant to 37 C.F.R. § 1.105.

Applicants have made a reasonable inquiry to determine keywords, ATCC accession numbers, other names by which the bacterial strains are known in the art or any other identifying information by which one skilled in the art would be able to distinguish the claimed strains. Applicants herein provide the deposit information from the International Depository Authority of Canada (IDAC) which is a Budapest Treaty approved depository. Applicants accordingly submit that they have provided sufficient information to identify the lactobacillus strains and thus have met the requirement to provide information under 37 C.F.R. § 1.105.

### **Enablement/Written Description**

The Examiner rejects claims 1, 4-6, 19, 29, 30, and 40 under 35 U.S.C. §112, first paragraph as not being enabled. The Examiner's rejection is based on his understanding that the names of the claimed bacteria "appear to be idiosyncratic and there is no publically available source for these bacteria" (Office Action, page 6). Applicants note that the strains were

deposited under the Budapest Treaty, and thus, Applicant has authorized IDAC to furnish samples according to applicable patent requirements.

The assignee of the present application, has deposited biological material under the terms of the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure with the following International Depository Authority: International Depository of Canada (IDAC), National Microbiology Laboratory, Public Health Agency of Canada, 1015 Arlington Street, Winnipeg, Manitoba Canada R3E 3R2 (present address). The deposit was made on the dates shown below and accepted by the IDAC and given IDAC Accession Numbers as shown below.

Strain Name	Deposit Date	IDAC Accession Number
K2	December 4, 2002	041202-1
ESI	December 4, 2002	041202-2
R2C2	December 4, 2002	041202-3
INIX	December 4, 2002	041202-4

A declaration by Éric Simard is attached which indicates that all restrictions on the availability to the public of IDAC Accession Numbers 041202-1, 041202-2, 041202-3, and 041202-4, will be irrevocably removed upon the grant of a patent based on the instant application, except as permitted under 37 C.F.R. § 1.808(b). Accordingly, Applicants request that the rejection be withdrawn.

The Examiner also rejects claims 1, 4-6, 19, 29, 30 and 40 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner states that "the instant specification has not provided how to obtain the claimed biological material, i.e., the lactobacillus strains or any structural information on the exopolysaccharide itself" (Office Action, page 8). Applicants submit that the claimed biological material is obtained from the specific *lactobacillus* strains. The specific exopolysaccharides are obtained using those strains.

Application No. 10/537,118

Amendment dated June 9, 2011

Reply to the Office Action dated December 9, 2010

As discussed above, these strains were deposited under the Budapest Treaty. Accordingly, Applicants request that the rejection be withdrawn.

## Indefiniteness

The Examiner rejects claims 1, 4-6, 19, 29, 30 and 40 under 35 U.S.C. § 112, second paragraph as being indefinite. The Examiner suggests that the term "exopolysaccharide" is unclear because the structure of the exopolysaccharide is not provided in the Specification. The Examiner states, for example, that "it is unclear if [the exopolysaccharide] is a homopolysaccharide or a heteropolysaccharide, if it is linear or branched" (Office Action, page 14). The Examiner indicates that since the bacterial strains are not sufficiently identified, the product-by-process nature of the claims leads to this indefiniteness rejection.

Applicants submit that the strains have been sufficiently identified to clarify which polysaccharides are included in the presently claimed compositions. Applicants request that the rejection be withdrawn.

#### Rejections under 35 U.S.C. §102(e)

The Examiner maintains the rejection of claims 1, 4-6, 19, 29, and 30 under 35 U.S.C. §102(e) as being anticipated by Simard *et al.* (U.S. 2006/0057131, hereinafter "Simard *et al.*"). The Examiner indicates that the Declaration under § 132 filed is not sufficient to overcome the anticipation rejection because the statement that the two applications "stand in the name of Biolactis Inc." is insufficient to overcome a §102(e) rejection.

Applicants herein provide a Declaration from Dr. Éric Simard. In the Declaration, it is explained that Dr. Simard, as one of the inventors, was responsible for inventing the subject matter of claims 1, 4-6, 19, 29, and 30. Specifically, as described in the Declaration, Dr. Simard asserts that the subject matter disclosed but not claimed in the cited U.S. Patent Application Publication No. 2006/0057131 (Simard *et al.*) and cited by the Examiner was conceived or invented by him, or by one of the other former co-inventors common to the '131 publication and

Reply to the Office Action dated December 9, 2010

the present application. Thus, Applicants submit that the disclosures of the Simard et al.

reference were not "by another". Applicants therefore request that the rejection be withdrawn.

Applicants believe the pending application is in condition for allowance. The favorable

actions of withdrawal of the pending rejections and allowance of the claims are requested.

Should there be any outstanding matters that need to be resolved in the present

application, the Examiner is respectfully requested to contact Mark J. Nuell, Ph.D. (Reg. No.

36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to

expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies

to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional

fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

Dated: June 9, 2011

Respectfully submi

Mark J. Nuell, Ph.D.

Registration No.: 36,623

BIRCH, STEWART, KOLASCH & BIRCH, LLP

12770 High Bluff Drive, Suite 260

San Diego, California 92130

(858) 792-8855

Attorney for Applicants

Attachments: Declaration of Dr. Éric Simard

Declaration of Availability of Deposits

Deposit and Viability Certificates